

**KENTUCKY BOARD OF PHARMACY**

via Zoom teleconference

<https://us02web.zoom.us/j/97333681907?pwd=NTBZMzhxVUI4alpjeDcyTnNKMUZOUT09>

**Meeting ID: 973 3368 1907**

**Password: 1UcfkN**

**Phone call in: 1-646-558-8656**

**April 28, 2020**

**1:00 p.m.**

**Board Meeting**

**Agenda**

**I. CALL TO ORDER**

**II. MINUTES**

- A. \*February 5, 2020
- B. \*March 16, 2020
- C. \*March 18, 2020
- D. \*March 25, 2020

**III. BOARD REPORTS**

- A. Executive Director
  - 1. \*eMars – January, February and March 2020
  - 2. \*Regulation Committee
  - 3. \*Advisory Council
- B. Committee Reports
  - 1. \*Advisory Council
  - 2. \*Regulation Committee
  - 3. PRN

**IV. CASES**

- A. \*Case Review
- B. \*Fines Report

**V. PENDING APPLICATIONS**

- A. \*Pharmacy Technician Summary
- B. \*Health and Wellness Pharmacy Inc – Non-resident pharmacy application
- C. \*The Bleeding and Clotting Disorders Institute – Non-resident pharmacy application

**VI. LEGISLATION/REGULATION**

- A. \*201 KAR 2:230
  - 1. \*Comments
- B. \*201 KAR 2:095, Pharmacist Interns
- C. \*RX Adaptation

D. \*COVID-19 Proposed Emergency Regulation Draft

**VII. CONTINUING EDUCATION**

A. \*CE Programs – 20-03, 20-05, 20-07, 20-08, 20-09, 20-12, 20-13

**VIII. NEW BUSINESS**

A. Advisory Council applications-Members will submit top 3 choices to [Larry.hadley@ky.gov](mailto:Larry.hadley@ky.gov) during the meeting.

1. \*Brian Hancock
2. \*Brian Yarde
3. \*Chad Thompson
4. \*Christina Hatfield
5. \*Hayden Pehl
6. \*Martika Martin
7. \*Paul Mahan
8. \*Ross Goetz
9. \*Thomas Kaye
10. \*Troy Huddleston
11. \*Wesley Rowe

B. \*Walmart KY Pharmacist Initiated Treatment Professional Services UTI Standing Order

\*Information included in Board Packet

## MINUTES

### KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

via teleconference

### BOARD MEETING

April 28, 2020

**CALL TO ORDER** A special called meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Poole called the meeting to order on April 28, 2020 at 1:02 p.m.

Members present: John Fuller, Ron Poole, Peter P. Cohron, Jill Rhodes, Jody Forgy and Craig Martin.

Staff: Larry Hadley, Executive Director; Anthony Gray, General Counsel; John Romines, Pharmacy and Drug Inspector; Paul Daniels, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Amanda Harding, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor, Melissa Hall, Administrative Specialist III and Darla Sayre, Executive Staff Advisor.

Guests: Cathy Hanna, APSC; Ralph Bouvette, APSC; Steve Hart; John Long; Trish Freeman; Brian Fingerson, KYPRN Committee; Joel Thornbury; Nichole Cover and Lavanya Peter, Park Duvall.

**MINUTES** On motion by Craig Martin, seconded by John Fuller and passed unanimously, the minutes of the February 5, 2020 Board Meeting were approved.

On motion by Jill Rhodes, seconded by Peter Cohron and passed unanimously, the minutes of the March 16, 2020 Board Meeting were approved.

On motion by Craig Martin, seconded by Jody Forgy and passed unanimously, the minutes of the March 18, 2020 Board Meeting were approved.

On motion by Craig Martin, seconded by Jill Rhodes and passed unanimously, the minutes of the March 25, 2020 Board Meeting were approved.

**BOARD REPORTS** Mr. Hadley requested the Board consider establishing a standing Regulation Committee consisting of nine members to include the Executive Director and one member of the inspection staff. The remaining members will be decided by application and appointment by the Board. The current members will be polled to determine if they wish to remain on the committee. Those remaining on the committee will have staggered terms. At the onset of the application process, half the applicants will be appointed for four year terms with the remaining half being appointed for three year terms. Once the committee members are established, all applicants in the future will be appointed for four year terms.

Craig Martin moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Mr. Hadley requested the Board consider the professional designation of the Advisory Council members. It has been suggested that the Board of Pharmacy allocate seats among the major segments of pharmacy practice in Kentucky. The proposed professional make-up is:

- Two (2) Chain Pharmacists
- Two (2) Independent Pharmacists
- Two (2) Hospital Pharmacists
- One (1) Academia Pharmacist
- One (1) Consultant Pharmacist
- One (1) Industry [not necessarily a pharmacist]

The proposed professional make-up of the Advisory Council will be considered during the normal cycle of term appointments. There is currently one vacancy on the Council from the resignation of Elizabeth Lovell. Three (3) council members have terms expiring December 31, 2020.

John Fuller moved to approve this request. Craig Martin seconded, and the motion passed unanimously.

**CASE REVIEW** Craig Martin moved to accept the Case Review Panel recommendations for:

**Revisit Case 17-0539 A.** Wholesale distributor permit holder allegedly engaged in unprofessional or unethical conduct regarding the source of distributed drugs. Permit holder allegedly failed to provide accurate and precise records of all goods shipped or received. Permit holder allegedly failed to employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs. Permit holder allegedly failed to provide adequate storage conditions. Permit holder allegedly failed to be properly licensed as a Wholesaler of Controlled Substances by the Cabinet for Health Services. Alleged Violations of Law: KRS 315.121(1)(a) and (h); KRS 315.402 (2); 201 KAR 2:105 Section 2 (4)(a) and (c) and Section 5(2)(d); and 902 KAR 55:010 Section 2. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine. Vote was unanimous.**

**Revisit Case 17-0539 B.** Non-resident wholesale distributor permit holder allegedly engaged in unprofessional or unethical conduct regarding the source of distributed drugs. Permit holder allegedly failed to provide accurate and precise records of all goods shipped or received. Alleged Violations of Law: KRS 315.121 (1)(a); KRS 315.402 (2); and 201 KAR 2:105 Section 2 (4)(c). **CRP Recommendation: There is sufficient evidence of a violation to warrant**

disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and two year probation with quarterly submission of the following documents; master vendor list, transactions list [list products shipped] and policy/procedures related to new orders.

Vote was unanimous.

**Revisit Case 19-0110 A.** Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by dispensing misbranded prescriptions. Alleged Violation of Law: KRS 315.121 (1)(a). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine. There were no modifications of the previous recommendation.**

**Revisit Case 19-0110 B.** Pharmacist-in-charge (PIC) allegedly engaged in unethical or unprofessional conduct by dispensing drugs for which a prescription order is required, without having first received a prescription order for the drug. Alleged Violations of Law: KRS 315.121 (2)(d) and (f). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine, additional 6 hours of continuing education. There were no modifications of the previous recommendation.**

**Revisit Case 19-0118 A.** Pharmacy permit holder allegedly sold misbranded drugs – ten compounded preparations dispensed with an assigned beyond use date past the expiration of a component. Permit holder allegedly sold an adulterated drug – one compounded preparation made with an expired ingredient. Permit holder allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Permit holder allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.065 (1), KRS 217.055 (1)(a), (2), 4(a), and 201 KAR 2:076 Section 2 (1). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine and one year submission of monthly reconciliation reports of compounding records for accuracy and completeness by PIC. Vote was unanimous.**

**Revisit Case 19-0118 D.** Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by dispensing misbranded prescriptions. Two compounded preparations

dispensed with an assigned beyond use date past the expiration of a component. PIC allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:076 Section 3 (2). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education. Vote was unanimous.**

**Revisit Case 19-0277 A and B.** Pharmacy permit holder allegedly sold misbranded and adulterated drugs. Sterile preparations from 15 separate lots were dispensed with an assigned beyond use date past the expiration of a component. One lot was compounded with an expired ingredient. Permit holder allegedly failed to compound sterile preparations pursuant to United States Pharmacopeia (USP) Chapter 797. Permit holder allegedly engaged in unethical or unprofessional conduct by aiding and abetting an individual with a revoked license to engage in the practice of pharmacy. Alleged Violations of Law: KRS 217.065 (1); KRS 217.055 (1)(a), (2), 4(a); 201 KAR 2:076 Section 2 (2); and KRS 315.121 (1)(g). Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by dispensing misbranded and adulterated prescriptions. PIC verified 8 lots of sterile preparations with an assigned beyond use date past the expiration of a component. PIC verified 1 lot of sterile preparations made with an expired ingredient. PIC allegedly failed to compound sterile preparations pursuant to United States Pharmacopeia (USP) Chapter 797. PIC allegedly engaged in unethical or unprofessional conduct by aiding and abetting an individual with a revoked license to engage in the practice of pharmacy. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (2); and KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$40,000 administrative fine, five year probation. Quarterly inspections for 2 years then semi-annually for remainder of probation. PIC to conduct monthly reconciliation for one year, must follow USP 797. Must specify unit packaging information for each lot in compounding records. Must maintain complete compounding records [to include total number of units compounded, the contents/volume of each unit, and the number of units of each package size] and have available upon inspection. Vote was unanimous.**

**Revisit Case 19-0277 C.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by dispensing misbranded prescriptions. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. Alleged Violations of Law: KRS 315.121 2(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0277 D.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by dispensing misbranded prescriptions. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. Alleged Violations of Law: KRS 315.121 2(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 A.** Pharmacy allegedly sold misbranded prescriptions, 244 prescriptions were dispensed labeled with a non-resident pharmacy's address. Alleged Violations of Law: KRS 217.065 (11)(b) and (12)(b). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$15,000 administrative fine, approved corrective action plan to prevent future occurrences. PIC must be involved in corrective action plan.**

**Revisit Case 19-0284 B.** Pharmacist in charge allegedly failed to implement an effective quality assurance program to identify system problems. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(a). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, approved corrective action plan to prevent future occurrences. PIC must be involved in corrective action plan.**

**Revisit Case 19-0284 C.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 40 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 D.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 34 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 E.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 21 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is**

**insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 F.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 20 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 G.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 17 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 H.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 I.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 J.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 K.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 12 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**



**Revisit Case 19-0284 L.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 11 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 M.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 11 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 N.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 9 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 O.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 7 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 P.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 6 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 Q.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 6 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 R.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 3 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 S.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 3 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 T.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 2 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 U.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 2 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0284 V.** Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 1 misbranded prescription labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

**Revisit Case 19-0295 A.** Pharmacy permit holder allegedly sold adulterated drugs, compounded preparations purported to be sterile were filtered through non-pharmaceutical grade filter in worse than ISO 5 air and no integrity testing was performed on the sterilizing filters. Compounded stock solution was further manipulated after sterilization in non-depyrogenated glassware. Pharmacy permit holder allegedly sold misbranded drugs, repackaged syringes and compounded preparations were assigned beyond use dates outside Food and Drug Administration (FDA) and United States Pharmacopeia (USP) guidance without supporting stability data. Pharmacy permit holder allegedly failed to follow the provisions of USP Chapter <797> when preparing sterile compounded preparations. Permit holder allegedly failed to

maintain compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.055 (1)(b); KRS 217.065 (1); KRS 315.121 (1)(h); and 201 KAR 2:076 Section 2(2), Section 4 (4). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$50,000 administrative fine, five year probation.**

- Quarterly inspections [to be paid by respondent within 30 days of invoice].
- Upon notice of cessation of sterile compounding then inspections semi-annually for remainder of probation.
- Provide list of and master formulation record for all compounded batch preparations and independent documentation of clinical need for product and need for the compounded form.
- Must comply with current USP 797.
- Shall not dispense any preparations that have failed laboratory testing.
- Shall not extend BUD on CSPs without stability, potency, endotoxin and sterility data performed to USP standards. Testing results submitted from the lab directly to the Board within seven days of results.
- Sterility, potency and endotoxin for every CSP prepared in batches or with extended BUD. Records must be maintained and accessible.
- Maintain a properly designated area for quarantined drugs, including a tracking mechanism for each drug and separation from other drugs if not prepared as a batch.
- Must use compounding sheets that are validated as accurate by the PIC.
- Label each prescription with information included in 201 KAR 2:076, Section 4(3)(a)-(k)
- Pharmacist must physically check each product in a PIC developed Board/President approved process. To be submitted with 30 days of fully executed Agreed Order.
- PIC shall immediately investigate and memorialize all ADEs, perform a root cause analysis and develop quality assurance measures designed to prevent a further occurrence. Reports shall be available upon request by the Board or its agents.
- PIC shall meet with pharmacy staff each quarter to conduct continuous quality improvement.
- PIC shall serve as the liaison between pharmacy and the Board.
- PICs shall attend Critical Point Boot Camp or similar training approved by the Board office within 6 months of the Agreed Order; thereafter, attendance at training is required within one year of appointment as PIC.
- All compounding personnel shall attend Critical Point Boot Camp or similar training approved by the Board office within 6 months of the Agreed Order.
- Sterility and/or potency testing of samples of sterile preparations confiscated by the Board's agents shall be paid by respondent.
- Document an ongoing quality control program and quality assurance procedures as required by 201 KAR 2:076 and USP. This program will be available at the request of the Board or its agents upon request.

- **PIC shall be responsible for quality assurance programs and the procurement, storage, security, disposition of drugs and the provision of pharmacy services. The owner will defer to the PIC on these matters.**

**Vote was unanimous.**

Peter Cohron seconded, and the motion passed unanimously.

## **PENDING APPLICATIONS**

Craig Martin moved to deny the first application presented. Jill Rhodes seconded, and the motion passed unanimously.

Peter Cohron moved to deny the second application presented. Jody Forgy seconded, and the motion passed unanimously.

Anthony Gray presented a non-resident pharmacy application from Health and Wellness Pharmacy Inc. in Tennessee. The Tennessee Board of Pharmacy has taken disciplinary action against this pharmacy. While in compliance, the Tennessee Board is not yet satisfied with the consultant inspection required. Peter Cohron moved to table this decision until a second consultant inspection is completed. John Fuller seconded, and the motion passed unanimously.

Katie Busroe presented a non-resident pharmacy application from The Bleeding and Clotting Disorders Institute in Illinois. The pharmacy performs sterile compounding and was originally planning to ship compounded sterile preparations (CSPs) into Kentucky. The last inspection was performed by the Illinois Board of Pharmacy on June 8, 2017, which was prior to the pharmacy beginning sterile compounding. No other entity has inspected or accredited the pharmacy since that time. The inspection by the Illinois Board of Pharmacy was a verbalization of how the sterile compounding would be performed. The Bleeding and Clotting Disorders Institute has indicated that they will not ship CSPs into Kentucky if that is a concern. Currently the pharmacy is only permitted in Illinois. John Fuller moved to table this decision until the pharmacy has been inspected for sterile compounding. Jill Rhodes seconded, and the motion passed unanimously.

## **LEGISLATION/REGULATION**

**201 KAR 2:230 Central Fill** The Board received comments from Walgreens and CVS on the proposed regulation amendment. The two issues were:

1. Requiring all pharmacists involved in the dispensing process be licensed with Kentucky; and
2. Requiring both the preparing pharmacy and dispensing pharmacy be listed on the label.

Representatives from the Regulation Committee stated that the intent was to open this practice to all pharmacies removing the restriction of being based in the Commonwealth and to allow for initial fills as well as refills. The amendments were more encompassing rather than restrictive.

Jill Rhodes moved to keep the regulation amendment as is and to continue the legislative review process. Peter Cohron seconded, and the motion passed unanimously.

**201 KAR 2:095 Pharmacist Interns** John Fuller moved to accept the committee recommendation for amending the regulation and submit to LRC. Peter Cohron seconded, and the motion passed unanimously.

**RX Adaptation** The Advisory Council submitted language for RX adaptation. Craig Martin moved to send this proposed language to the Regulation Committee for insertion in an existing or creation of a new regulation. Peter Cohron seconded, and the motion passed unanimously.

**COVID-19 Proposed Emergency Regulation Draft** Anthony Gray advised that this draft was submitted prior to the signed Executive Order amending KRS 315.010(22) issued by the Secretary Brown on Friday, April 24<sup>th</sup>. This draft language was utilized in the Executive Order expanding the 'Practice of Pharmacy' to allow for the initiation, ordering and administering of COVID-19 tests by pharmacists. Jill Rhodes questioned if the wording should be amended to include health facility as well as pharmacy and to allow this practice to be done by pharmacist interns and pharmacy technicians. After much discussion, the Board requested that this draft be rewritten without specific COVID-19 language to be utilized for future events. The Board allowed the existing Executive Order issued April 24, 2020 to remain as is.

## **NEW BUSINESS**

**Advisory Council Vacancy** Mr. Hadley informed the Board that due to the resignation of Elizabeth Lovell, there was a vacancy on the Advisory Council. Applicants who submitted an application last fall were contacted for their continued interest in serving. Based on the Board decision regarding professional designation in determining appointments to the council, three applicants were submitted for voting. Votes were cast by text or email to Mr. Hadley. Mr. Hadley informed the Board that Wesley Rowe received the majority of the votes. Peter Cohron moved to appoint Wesley Rowe to the Council to serve the remainder of Elizabeth Lovell's term expiring December 31, 2022. Jody Forgy seconded, and the motion passed unanimously.

**Walmart KY Pharmacist Initiated Treatment Professional Services UTI Standing Order** Craig Martin moved to table this request until the next Board meeting to allow a representative be in attendance for questions. Peter Cohron seconded, and the motion passed unanimously.

**ADJOURNMENT** On motion by Craig Martin, seconded by Peter Cohron and passed unanimously, President Poole adjourned the meeting at 3:17 p.m. The next regularly scheduled meeting begins at 9:00 am on May, 27, 2020 at the Kentucky Board of Pharmacy in Frankfort, KY or via teleconference.

Larry A. Hadley  
Executive Director